MAR 17 2006

SECTION 10: 510(K) SUMMARY

K000359

Name and Address of Manufacturer:	Imatron, Inc. 389 Oyster Point Blvd. South San Francisco, CA 94080
Contact:	J.A. Coduto Director of Regulatory Affairs Phone: 503-638-5500 FAX: 503-638-6328 email: jcoduto@imatron.com
Establishment Registration Number:	2936804
Common and Proprietary Names:	Common Names: CT scanner system; Computed tomography X-ray system; Electron beam scanner system; Scanner system; CT angiography system; Electron beam angiography system Proprietary Name: EBT Ultrafast® CT scanner system; Ultrafast CT scanner system; C-100, C-150, C-150LXP or C-150XP scanner systems
Device Class:	Class II
Classification Name:	21 CFR 892.1750/Procode: 90 JAK Computed tomography x-ray system 21 CFR 892.1600/Procode: 90 IXI Angiography x-ray system
Performance Standards:	The Imatron EBT scanner system meets the applicable requirements of the FDA Performance Standard for Ionizing Radiation Emitting Products (i.e., 21 CFR Sections 1020.30, 1020. 31, 1020. 32, and 1020.33).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

J.A. Coduto
Director, Regulatory Affairs
Imatron, Inc.
389 Oyster Point Blvd.
South San Francisco, CA 94080

Re: K000359
Electron Beam Tomographic ("EBT") Scanner Systems
Ultrafast® Computed Tomographic (CT) Scanner Systems
Dated: February 1, 2000
Received: February 4, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Coduto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: _____

Indications for Use:

The prior intended and cleared uses of the device here in question, i.e., the Imatron Electron Beam Tomography ("EBT") Scanner, remain unchanged. In general, the Imatron EBT Scanner is designed -- as are all similar devices -- to produce cross sectional images (i.e., thin slices) of the human anatomy for use by the physician as an aid in diagnosing disease and other conditions. In this instance, such images are produced via helical (i.e., continuous volume or dynamic) or stationary (i.e., static) and/or prospectively triggered scanning.

Imatron's device is -- as are some of the predicate devices -- also intended to be used for clinical situations requiring determination of specific quantitative information, such as the determination of calcium or other materials in bone, tumors, or organs.

The Imatron EBT scanner system -- when used angiographically -- is intended to combine the capabilities of both a tomographic and angiographic system. When used for this purpose, the system is intended to perform Electron Beam Angiography, i.e., "EBA". More specifically, the EBT system is intended:

1. to function as a diagnostic x-ray system to produce two and three dimensional images of the heart, blood vessels, or lymphatic system from a volume of computer reconstructed cross-sectional images from x-ray transmission data from the same axial plane taken at different angles;

2. to permit radiologic visualization during or after injection of a contrast medium; and

3. to permit the transmission data from certain three dimensional images to also be presented in time-sequenced or cine fashion.

Finally, such EBA system is intended to be used consistent with those already classified and set forth in 21 CFR Sections 892.1600 and 892.1750.

The Imatron EBT scanner system is also intended for use by the physician as an aid in the diagnosis of lung anomalies.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000359

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)